

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: DAVOL, INC./C.R. BARD, INC.,
POLYPROPYLENE HERNIA MESH
PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Johns v. C.R. Bard et al.,
Case No. 2:18-cv-01509
Mileansi v. C.R. Bard et al.,
Case No. 2:18-cv-01320

ORDER

During the June 8, 2021 case management conference for this multidistrict litigation (“MDL”), the parties explained to the Court that they disagreed about whether Plaintiffs’ replacement expert, Dr. Michael G. Beatrice, Ph.D., for Plaintiffs’ former regulatory expert, Dr. David A. Kessler, M.D., offered opinions beyond the scope of Dr. Kessler’s original opinion. In other words, the dispute is whether Dr. Beatrice can fairly be considered a substitute expert, which the Court stated it would permit, as opposed to a new expert offering new opinions. Defendants seek an order clarifying the proper scope of Dr. Beatrice’s deposition on these grounds before the deposition on June 22, 2021. The Court permitted briefing.¹ (ECF No. 448.) For the reasons that follow, Dr. Beatrice’s deposition cannot address his new and different opinions.

Although Plaintiffs did not file a motion seeking leave to substitute a new expert witness, the Court views this as the functional equivalent. Courts have considered whether to limit expert testimony in response to motions to substitute experts even though

¹ The parties filed their briefs in both *Johns* and *Milanesi*. The Court cites to the briefs in *Johns*, Case No. 18-cv-1509, for the sake of simplicity.

such arguments “are more properly the subject of a motion *in limine*.” *In re Northrop Grumman Corp. ERISA Litig.*, No. CV 06-06213-AB (JCx), 2016 WL 6826171, at *3 (C.D. Cal. April 7, 2016). Motions to substitute experts are most commonly construed as a “request to modify a scheduling order” under Federal Rule of Civil Procedure 16(b). *E.g., id.* at *2; *see Medspace, Inc. v. Biothera, Inc.*, No. 1:12-cv-179, 2014 WL 1045960, at *2 (S.D. Ohio Mar. 17, 2014). Accordingly, trial courts evaluate whether the party seeking to substitute an expert has good cause to do so and whether the other party will be prejudiced. *E.g., Medspace*, 2014 WL 1045960, at *2. It is undisputed that Dr. Kessler’s selection to co-chair President Joe Biden’s COVID-19 response initiative has given Plaintiffs good cause to substitute an expert for Dr. Kessler. Thus, the only question is whether Defendants will be prejudiced by this substitution, specifically whether they will be prejudiced if the scope of Dr. Beatrice’s deposition is not limited as they request.

To determine whether the nonmoving party will be prejudiced, courts typically limit the substitute expert’s opinions and testimony “to the subject matter and theories already espoused by the former expert.” *Lincoln v. Nat’l Life Ins. Co. v. Transamerica Finan. Life Ins. Co.*, No. 1:04-CV-396, 1:06-CV-317, 2010 WL 3892860, at *2 (ND. Ind. Sept. 30, 2010); *see also Roberts ex rel. Johnson v. Galen of Va., Inc.*, 325 F.3d 776, 784 (6th Cir. 2003) (concluding the district court did not err when it required that the substitute expert “not deviate from [the prior expert’s] conclusions”). Substitute expert opinions and testimony must be “substantially similar” to and “cannot be contrary to or be inconsistent with” those presented by the original expert. *Shipp v. Arnold*, No. 4:18-cv-4017, 2019 WL 4040597, at *3 (W.D. Ark. Aug. 27, 2019); *see also Medspace*, 2014 WL 1045960, at *4. “This is not to say that a new expert must ‘simply adopt the prior expert’s

conclusions verbatim—in effect, doing little more than authenticating and confirming the prior expert’s conclusions.” *Shipp*, 2019 WL 4040597, at *3 (quoting *Lincoln*, 2010 WL 3892860, at *2). “Rather, the substitute expert ‘should have the opportunity to express his opinions in his own language after reviewing the evidence[.]’” *Lincoln*, 2010 WL 3892860, at *2 (quoting *Morel v. Daimler-Chrysler Corp.*, 259 F.R.D. 17, 22 (D.P.R. 2009)). But ultimately, “[t]he purpose of allowing substitution of an expert is to put the movant in the same position it would have been in but for the need to change experts; it is not an opportunity to designate a better expert.” *U.S. ex rel. Agate Steel, Inc. v. Jaynes Corp.*, No. 2:13-cv-01907, 2015 WL 1546717, at *2 (D. Nev. Apr. 6, 2015).

Defendants argue that Dr. Beatrice offers the following opinions beyond the scope of Dr. Kessler’s opinions: design control, complaint handling, Material Safety Data Sheets (“MSDS”), and more detailed Ventralight ST opinions. (ECF No. 449 at PageID #PageID #22732–37.) Dr. Beatrice steps outside of the bounds of Dr. Kessler’s report and provides new and different opinions on significant issues. And given the timing of this substitution, Defendants will be prejudiced if Dr. Beatrice is permitted to offer these new opinions and his deposition is not limited to only those opinions that are substantially similar to Dr. Kessler’s opinions.

First, design control. Defendants argue that Dr. Beatrice explains design controls and the regulations for the Ventralight ST and Ventralex devices, including International Organization Standards, design inputs/outputs, failure modes and effects analysis, design failure modes and effects analysis, and corrective and preventative actions. Plaintiffs admit that these opinions were not offered by Dr. Kessler and focus on prejudice to Defendants (ECF No. 452 at PageID #23329), which the Court discusses *infra*. As for

the Ventralex opinions, Dr. Kessler discusses the design controls in relation to the Ventralex device (*e.g.*, ECF NO. 499-2 at PageID #22970) and so Dr. Beatrice may offer his own broader and more detailed opinion on the same topic.²

Second, complaint handling. Although Dr. Kessler summarized several complaints to note that there were known failure modes of the Ventralex device, Defendants assert that Dr. Beatrice opines that Defendants failed to properly handle and track complaints and provides greater detail and summaries of additional complaints. (ECF No. 449 at PageID #22734.) The Court agrees. Dr. Kessler did not offer an opinion about the adequacy of Defendants' complaint handling practices. Plaintiffs do not dispute that Dr. Beatrice's opinion is different, and again they focus on prejudice. (ECF No. 452 at PageID #23328.)

Third, the MSDS opinion. Defendants contend that Dr. Beatrice offers an MSDS opinion in his report while Dr. Kessler did not, though Dr. Kessler did in his deposition. (ECF No. 449 at PageID #22735.) Plaintiffs' only response is that Dr. Kessler invited Defendants to question him on this opinion during his deposition, but that Defendants elected not to. (ECF No. 452 at PageID #23328.) In his deposition, Dr. Kessler offered a rebuttal opinion to Defendants' expert, Dr. Tillman. (ECF No. 452-1 at PageID #23338.) But Dr. Beatrice offers a stand-alone opinion about whether Defendants' FDA submission should have disclosed the polypropylene MSDS's Medical Caution Statement and whether the MSDS should have led Defendants to warn their end users. (ECF No.

² Defendants' quality management systems, including design controls, are the same across Defendants' devices. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ---, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 81821, at *6 (S.D. Ohio Jan. 11, 2021). However, Dr. Kessler's opinion narrowly considered the alleged short-comings of the Ventralex device, including buckling of the mesh and the infection risk with the ePTFE. (ECF No. 449-2 at 22952–71.) This renders Dr. Kessler's opinions fundamentally different than Dr. Beatrice's opinions on this matter.

449-3 at PageID #21201.) This is substantially different than the MSDS opinion Dr. Kessler offered to demonstrate his disagreement with Dr. Tillman.

Finally, Ventralight-ST-specific opinions unrelated to design controls discussed *supra*. Defendants contend that Dr. Beatrice's report contains new regarding the Ventralight ST device.³ (ECF No. 449 at PageID #22735–36.) These opinions include that Defendants failed to adequately test the ST coating and determine what tests were adequate; that the Ventralight ST's Special 510(k) submission was inappropriate; that Defendants should have obtained Pre-Market Approval; that the Ventralight ST was adulterated; and that the Ventralight ST was misbranded. (*Id.* at PageID #22736.) Plaintiffs offer no answer to this contention; they only contend the differences are not prejudicial. (ECF No. 452 at PageID #23327.) The Court agrees that Dr. Beatrice offers new opinions. Although Dr. Kessler generally discusses some topics on which Dr. Beatrice opines, Dr. Kessler does not offer an opinion himself. Accordingly, Dr. Beatrice's specific Ventralight ST opinions are new and different opinions.

Plaintiffs counter that Dr. Beatrice's new and different opinions are not prejudicial to Defendants, meaning the Court should decline to limit the deposition. (ECF No. 452 at PageID #23329–33.) Plaintiffs assert that any differences “are discreet and easily addressed in a deposition,” that the documents Dr. Beatrice rely on are the same and thus Defendants cannot claim surprise, and that Defendants have other experts that have addressed Dr. Beatrice's new opinions. (*Id.* at PageID #23329–31.) Plaintiffs also argue that Defendants are not prejudiced by Dr. Beatrice's complaint opinion because it is only a paragraph. (ECF No. 452 at PageID #23328.) The Court disagrees.

³ Defendants agree that Dr. Beatrice's and Dr. Kessler's opinions regarding the Ventralight ST's Instructions For Use are similar. (ECF No. 449 at PageID #22735–36.)

Some trial courts have permitted a substitute expert to offer different opinions because the nonmoving party cannot show they will suffer prejudice. Courts consider whether the nonmoving party “had notice of the possibility of substitution,” were “not surprised by new subject matter,” and “ha[s] ample time to formulate a response and prepare cross-examination.” *Morel*, 259 F.R.D. at 21 (considering motion to substitution under Federal Rule of Civil Procedure 37(c)(1)). Other courts have also considered the “difficulty in curing any prejudice,” such as by having the nonmoving party’s experts respond, and if such a cure can be achieved in a timely manner before trial. *Sikkelee v. Precision Airmotive Corp.*, No. 4:07-CV-00886, 2021 WL 392101, at *7 (M.D. Pa. Feb. 4, 2021). The possible prejudice to the *moving* party if the new or different opinions are not permitted is also important. *Id.* at *8.

Although some factors suggest that Defendants will not be prejudiced, the cumulative weight of the factors counsels not allowing Dr. Beatrice to offer is different opinions, most imminently not permitting those opinions as a subject matter of his deposition. Defendants have had some notice that Dr. Kessler will be replaced and there is some overlap between Dr. Beatrice’s different opinions and other opinions in this trial. The fact remains, however, that Dr. Kessler was Plaintiffs’ star expert witness and that Defendants have already expended substantial time and effort responding to the crux of Dr. Kessler’s opinions. Forcing Defendants to counter Dr. Beatrice’s new opinions will inevitably delay their pretrial preparations. Moreover, this substitution, though admittedly unavoidable, comes at the equivalent of the ninth hour in a complex MDL. In a normal case, six weeks between the expert’s deposition and the first day of trial is ample time to file *Daubert* motions, ask for permission to designate a rebuttal expert if necessary, and prepare for cross-examination at trial. But in an MDL, that is not the case.

The Court also has its doubts that any prejudice can be cured simply during cross-examination given the nature of some of Dr. Beatrice's opinions. The Court is particularly cognizant of Dr. Beatrice's new Ventralight-ST-specific opinions. To have additional experts opine on these issues inevitably strengthens Plaintiffs' case. A prevalent concern of courts while adjudicating motions to substitute is to put the moving party in the same position, but not to give them a "windfall" by permitting them to appoint a better expert. *Lefta Assocs., Inc. v. Hurley*, No. 1:09-cv-2487, 2013 WL 12239510, at *4 (M.D. Pa. Feb. 13, 2013). And finally, if Defendants need to designate a rebuttal expert to Dr. Beatrice, that will drastically compound the timing issues already present with the forthcoming *Daubert* motion.

Importantly, Plaintiffs cannot claim that *they* will be prejudiced if the parties are not permitted to depose Dr. Beatrice on his new and different opinions. *Id.* at *4. In *Sikkelee*, it was crucial that the substitute expert's new and different opinion filled a unique role in the moving party's case, meaning it would injure the moving party not to permit the opinion. 2021 WL 392101, at *8. Plaintiff does not claim that Dr. Beatrice's different opinions fill a singular role in their cases. Plaintiffs only generically argue that they will be prejudiced. (ECF No. 452 at PageID #23332.) Indeed, Plaintiffs admit that Dr. Beatrice's new opinions are shared by other experts, such as Mr. Quick. (ECF No. 452 at PageID #23327.)

Plaintiffs also argue that limiting Dr. Beatrice's deposition now may lead to duplicative depositions and briefing in subsequent bellwether trials. (*Id.* at PageID #23332.) The Court is unconvinced that limiting the deposition will hasten the inevitability of additional depositions and motions as this MDL unfolds and new issues emerge. It especially unclear how Dr. Beatrice's Ventralight ST opinions can significantly impact subsequent bellwether cases when those bellwethers do not pertain

to the Ventralight ST device. Plaintiffs had the opportunity to designate an FDA regulatory expert like Dr. Kessler and to have that expert offer specific Ventralight ST opinions. They did not; instead, they offered Dr. Kessler, who focused on the Ventralex device. Accordingly, Dr. Beatrice's deposition will be limited to those opinions that are substantially similar to Dr. Kessler's opinions.

It is worth noting what this order does and does not decide. Although Defendants raised this issue in relation to Dr. Beatrice's deposition, this order necessarily addresses whether Dr. Beatrice can offer his new opinions at all, *i.e.* in his report as well as during his deposition. However, Defendants did not move to strike this opinion under Rule 37(c). This opinion does not address whether Dr. Beatrice's opinions are admissible, nor does the Court view this opinion as sua sponte striking any parts of Dr. Beatrice's report. This order also does not preemptively prohibit Dr. Beatrice from offering opinions that Defendants claim Dr. Kessler disclaimed. (ECF No. 449 at PageID #22732.) Defendants do not specifically point to any of Dr. Beatrice's opinions, and the Court declines to issue such a sweeping prohibition without the benefit of additional detail. It is incumbent on the parties to file subsequent motions if they seek to have these issues adjudicated.

IT IS SO ORDERED.

6/18/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE